K013703

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8.0 510(k) Summary

510(k) Summary

(As Required by 21 C.F.R. §807.92)

Submitted by: Sachi Kataoka
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Date of summary: This summary was prepared on October 1, 2001.

Device name: The device names are the Sanyo CO_2 Incubators, Models Nos. MCO-17AC, MCO-17AIC, MCO-20AIC, and MCO-175M.

Common name: CO_2 Incubators

Classification names:

Regulation Number & ProCode	Classification Name
21 CFR § § 884.6120 ProCode 85 MQG	Embryo Incubator/Assisted Reproduction Accessory

Predicate Devices: CO_2 Incubators cleared for ThermoQuest Corp. (K001524, 7/12/2000) and Kendro Laboratory Products, L.P. (K002805, 11/9/00).

Modifications: One of the subject devices provides a model equipped with UV-based decontamination control, as opposed to either HEPA filtration or heat disinfection which are the methods employed as the primary means of decontamination control by the predicate devices.

Intended Use: To provide an environment with controlled temperature, CO_2, (other gases), and elevated humidity for the development of ova or embryos at or near body temperature.

Technological Characteristics: The devices are microprocessor controlled to regulate temperature, CO_2 density, humidity level, alarms, and other parameters. The interior chamber consists of either stainless steel or a copper enriched stainless steel alloy, and housed within an insulated coated steel exterior cabinet.

Operational accessories include options for an automatic CO_2 cylinder switchover system, CO_2 regulator, communication ports, and data acquisition software. Each device is a bench top or floor standing unit and direct line AC powered.

The microprocessor manages continuous feedback from data entry, set points, and alarm parameters via a PID (proportional, integral, and derivative) algorithm. In response to chamber demand, and ambient temperature, the control system apportions energy to multiple independent heating elements. These are located in various zones around the chamber interior to control CO_2, temperature and other parameters.

Depending on the model, temperature is achieved using either a direct heat air jacket (DHA) or water jacket each operated off of a heater unit(s) responding to a thermistor sensor or Pt 100Ω.

Temperature range for all models is from 5°C above ambient to +50°C with 0.1% set-point increments. Chamber temperature uniformity is better than 0.25°C.

Air humidification is achieved by natural vaporization of distilled water. The humidity specification is >95%± 5%.

CO_2 control is maintained by infrared sensor or by a thermal conductivity probe, depending on the model. The IR sensor operates independently of RH and temperature changes, and is automatically self-calibrating every 4 hours. A CO_2 sensor sampling port allows access for confirmation of CO_2 density. The CO_2 range is 0 to 20% in 0.1% set-point increments for all Models. The O_2 level can be set to 2-18%, or 22-70% using Zirconia solid-state electrolyte sensor technology.

The Sanyo models are equipped with some or all of the following alarms: audible and visual alarms for: temperature, CO_2 deviation, door open, overheat, water level, and remote alarm contacts.

The MCO-20AIC incubator is designed with a programmable UV decontamination system, coupled with copper enriched stainless steel walls, autoclavable shelving, and plenum components. Vent intakes are fitted with sub-micron filters.

The remaining models employ either copper enriched stainless steel interior with sub-micron filters or simply sub-micron filters.

Testing

Performance and safety testing were performed to verify operating specifications, EMC safety, and UV strength.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2001

SANYO North America Corporation
% Mr. Sachi Kataoka
SANYO Sales & Supply Company
SANYO Scientific
900 N. Arlington Heights Rd.
ITASCA IL 60143-2844

Re: K013703
Trade/Device Name: Sanyo CO_2 Incubators
Regulation Number: 21 CFR 884.6120
Regulation Name: Assisted reproduction accessories
Regulatory Class: II
Product Code: 85 MQG
Dated: October 30, 2001
Received: November 8, 2001

Dear Mr. Kataoka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K013703

Device Name Sanyo CO_2 Incubators Model Nos. MCO-17AC, MCO-17AIC, MCO-20AIC, and MCO-175M

Indications for Use To provide an environment with controlled temperature, CO_2, (and other gases), and elevated humidity for the development of ova or embryos.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

David A. Gregson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013703